

EXHIBIT F

John Dalimonte

From: John A. Dalimonte [johndalimonte@kdlaw.net]
Sent: Wednesday, June 03, 2015 7:21 AM
To: 'MacFarland, William C'
Cc: 'Simms, Joshua'
Subject: RE: C.R. Bard
Attachments: Exh 1190.pdf; Exh 1191.pdf; Exh 517.pdf; Exh 697.pdf; Exh 682.pdf; Exh 672 Updated.pdf; Exh 945.pdf; PT Exh 6 - 848 F. Supp. 287.pdf

Good morning gentlemen:

We recently received a favorable ruling allowing us to share with you documents that C.R. Bard, Inc. has held back from the FDA concerning its IVC filter product line. As you know, the Bard Simon Nitinol Filter was the predicate device to the Recovery filter which was cleared through the 510(k) process as the substantially equivalent. Bard then used the Recovery filter to serve as the predicate device for its subsequent filter product line knowing full well that it was not the substantial equivalent and concealed information relating to the safety of this device from the FDA, doctors and public in order to gain a competitive advantage. The same was true with some of its successors such as the G2 filter. I have hundreds of documents that I can share, but it still only the tip of the iceberg. In the meantime, attached are a couple of documents for your review. I intend to forward all recently made public documents. I have many more concerning off label promotion, lack of sufficient testing prior to market, discovery of improper testing after market, refusal to follow up with post market surveillance after several physicians and medical centers reported significant failure rates, admission of a reactive/redesign policy essentially using people as Guinea pigs to test and get their product to market.

This is the same conduct, if not worse, than what took place in the past that led to criminal indictments and millions in fines. I would be happy to set up a drop box account with a link to share these documents, or can place them on a flash drive and send them to you. Please let me know what you prefer.

Ironically, Bard's defense at this trial was that they shared all their documents with the FDA and that the FDA gave their blessing. Feel free to call me anytime on this matter at the number below.

John A. Dalimonte
617-367-3311

From: MacFarland, William C [mailto:William.MacFarland@fda.hhs.gov]
Sent: Tuesday, April 28, 2015 4:41 PM
To: John A. Dalimonte
Cc: Simms, Joshua
Subject: RE: C.R. Bard

Thank you for this information, John. It will help keep me up to date with the IVC filter issue.

Sincerely,
Bill MacFarland

Tel: 301-796-5547
Fax: 301-847-8128
Email: william.macfarland@fda.hhs.gov

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